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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,822	05/26/2000	Gyorgy Lajos Kis	OP/V-30969A	9338

1095 7590 01/10/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/580,822

Applicant(s)

KIS ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23,25-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23,25-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 21-23, 25-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (U.S. Patent No. 5,052,558) in view of MaCartney et al. (U.S. Patent No. 5,460,283).

With respect to claims 21, 22, 26, Carter discloses a method of packaging and steam sterilizing a pharmaceutical product such as saline solution (col.2, lines 62-67). A semi-rigid squeezable polypropylene bottle **20** is filled with a pharmaceutical product and once the bottles are sealed and prepared for sterilization, they are inserted into an autoclave. See col.4, lines 47-60. The autoclave sterilizes the bottles using an application of steam at temperatures of 121 °C. Although Carter teaches that the bottles **20** and caps **22** are “preferably made of a polypropylene material...it is recognized that there are other polymeric materials which might be suitable....” See col.2, lines 54-62. Carter does not specifically teach forming the cap from a material with a modulus of elasticity different from polypropylene.

MaCartney et al. discloses a polyethylene cap, for use with containers, particularly polypropylene containers. MaCartney et al. teaches that polypropylene containers and caps have the inherent characteristic of “drawing back” at the point of contact, thereby reducing the contact pressure at the seal interface and impairing or destroying the integrity of the seal. See col.1, lines 42-48. As a solution, MaCartney et al. proposes using a stiff polyethylene cap for the polypropylene bottle, which maintains long term sealing engagement between the sealing

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surfaces. See col.2, lines 64-67 and col.4, lines 35-39. As Carter recognizes the expansion and contraction of polypropylene during sterilization and the subsequent relaxing of the seal (col.3, lines 42-46), it would have been obvious to one of ordinary skill in the art to replace the polypropylene cap of Carter with a polyethylene cap for the reasons disclosed by MaCartney et al..

As to claims 23 and 27, it is deemed within the skill of one in the art to choose an appropriate bottle thickness for the polypropylene bottle 20 of Carter. As these types of bottles are extremely common in the art, there is no invention of choosing a suitable wall thickness.

With respect to claim 25 and 29, the cap of MaCartney et al. is disclosed to be polyethylene and “stiff”. High-density polyethylene is known for its stiffness. Thus, it is deemed obvious that the polyethylene employed by MaCartney et al. is high density.

Response to Arguments

3. Applicant's arguments filed 27 October 2005 have been fully considered but they are not persuasive.

4. Applicant argues that “the cited references when considered as a whole do not suggest the desirability and thus the obviousness of replacing a polypropylene cap with a polyethylene cap on a filled polypropylene bottle subjected to an autoclaving process.” Applicant submits that since Carter employs a silicone gasket to prevent leakage that occurs when the polypropylene expands and contracts during autoclaving, there is no motivation to provide the polyethylene cap of MaCartney et al. which achieves the same purpose.

The Examiner respectfully disagrees. In engineering design, it is well-known to provide

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redundant systems in order to achieve a certain factor of safety. As the only difference between Carter and the present invention is the material from which the cap is made and as Carter clearly teaches that "it is recognized that there are other polymeric materials which might be suitable...", it is well within the purview of one of ordinary skill in the art to choose the cap material disclosed by MaCartney et al., which would further enhance the leakage-free characteristics of the container. Moreover, the polyethylene cap of MaCartney et al. would have provided the necessary redundancy to the seal for instances when the gasket fails.

5. Applicant further argues that the present inventors were not concerned with the particular problem encountered by Carter and thus, "one skilled in the art would not utilize Carter to solve the problem of sealing between the nozzle tip and cap since Carter was concerned with the problem of leakage and loose caps." Again, the Examiner disagrees with Applicant's assessment of the combination. Firstly, it is noted that Carter was not combined with applicant's invention in a rejection and thus it is not necessary for Carter to teach or solve the problem of sealing between the nozzle tip and cap. Secondly, it is not necessary for any of the references used in the combination to recognize the problem solved by applicant's invention. The mere fact that the references relied on by the Examiner fail to evince an appreciation of the problem identified and solved by applicants is not, standing alone, conclusive evidence of the nonobviousness of the claimed subject matter. The references may suggest doing, what an applicant has done even though workers in the art were ignorant of the existence of the problem. See *In re Gershon*, 152 USPQ 602 (CCPA 1967).

6. Applicant subsequently argues that the combination of Carter with MaCartney et al. does not solve the problem of sealing of the nozzle tip and cap when sterilizing a polypropylene

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bottle. However, the claims do not require such and thus, it is not necessary for the combination to recognize or teach solving the problem.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

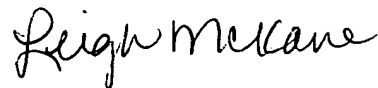
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leigh McKane
Primary Examiner
Art Unit 1744

elm
9 January 2006